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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,751	09/22/2003	Michael T. Greene	T0217.10U	1900

7590

06/27/2005

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EXAMINER

WIEKER, AMANDA FLYNN

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/667,751

Applicant(s)

GREENE ET AL.

Examiner

Amanda F. Wieker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 15,20-23,44-46,50 and 51 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-49 is/are allowed.
- 6) ☒ Claim(s) 1-14,23-36,41 and 42 is/are rejected.
- 7) ☒ Claim(s) 16-19 and 37-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/22/03
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:
Species A, as in Figure 2;
Species B, as in Figure 5; and
Species C, as in Figure 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 25 appear generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Thomas Saitta on 21 June 2005 a provisional election was made without traverse to prosecute the invention of Species A, claims 1-14, 16-19, 24-42 and 47-51. Affirmation of this election must be made by applicant in replying to this Office action. Claims 15, 20-23 and 43-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 22 September 2003 has been considered by the examiner.

Specification

5. The disclosure is objected to because of the following informalities: On page 9, at line 10, it appears that the reference to Figure 5 is improper. This should be amended to refer to Figure 4, such that the specification agrees with the drawings.

Appropriate correction is required.

Claim Objections

6. The claims are misnumbered. There are two claims labeled as "claim 23" (page 16). In this office action, any reference to "claim 23" refers to the second recitation of claim 23, as the first has been withdrawn, due to the Election of Species requirement. Appropriate correction is required.

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7. Claims 25 and 47 objected to because of the following informalities: In line 4, there is insufficient antecedent basis for "said helmet". The helmet is not introduced into the claim until line 5. Appropriate correction is required. Claim 47 contains an identical problem.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-6, 9-10, 23-28, 31-32 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 2,681,058 to Mathues.

Mathues discloses a craniomaxillofacial distraction device comprising:

head mounting means (10) for securing said device to the head of a patient in a relatively fixed manner, said head mounting means comprising a helmet, wherein relative motion between the helmet and the head of the patient is limited, and wherein said helmet distributes compressive forces such that localized pressure points are avoided;

support means (12, 14, 30, 48) for receiving distraction means, said support means being connected to said head mounting means; and

distraction means (58, 60) for applying distracting forces to treat craniofacial anomalies, for example, in the jaw of the patient, said distraction means being mounted onto said support means and connected to the jaw of the patient.

The support means comprise a generally vertically oriented support rod member (30).

The support means comprise an anterior mounting member secured to the helmet (12).

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The support means comprise a mounting stem (14) extending from the anterior mounting member, and the support rod member (30) is connected to the mounting stem (14).

The support means comprise a crossbar assembly comprising a generally horizontally disposed crossbar rod member (48).

The crossbar assembly is adjustable relative to the support rod member (30) (via 46).

The helmet is open on top.

The helmet comprises adjustment means for altering the configuration of the helmet (see column 2, lines 8-9; "adjustable").

The support means comprise multi-directional orientation means (left-to-right movement along 14's axis; vertical movement along 30's axis; and 46 being a universal joint), such that orientation of the support rod member is adjustable relative to the head mounting means.

10. Claims 1-6, 9-10, 23-28, 31-32 and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent Number 5,890,891 to Doyle.

Doyle discloses a craniomaxillofacial distraction device comprising:

head mounting means (28) for securing said device to the head of a patient in a relatively fixed manner, said head mounting means comprising a helmet, wherein relative motion between the helmet and the head of the patient is limited, and wherein said helmet distributes compressive forces such that localized pressure points are avoided;

support means (50, 54) for receiving distraction means, said support means being connected to said head mounting means; and

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distraction means (82) for applying distracting forces to treat craniofacial anomalies, for example, in the jaw of the patient, said distraction means being mounted onto said support means and connected to the jaw of the patient.

The support means comprise a generally vertically oriented support rod member (50).

The support means comprise an anterior mounting member secured to the helmet (14).

The support means comprise a mounting stem (26) extending from the anterior mounting member, and the support rod member (50) is connected to the mounting stem (26).

The support means comprise a crossbar assembly comprising a generally horizontally disposed crossbar rod member (66, 74, 78).

The crossbar assembly is adjustable relative to the support rod member (vertically).

The helmet is comprised of

The helmet is open on top.

The helmet comprises adjustment means for altering the configuration of the helmet (see column 5, lines 2; "Velcro®").

The support means comprise multi-directional orientation means (universal joint 26), such that orientation of the support rod member is adjustable relative to the head mounting means.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 7-8, 10-12, 14, 29-30, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathues in view of U.S. Patent Number 6,428,494 to Schwenn et al.

Mathues discloses the previously described craniomaxillofacial distraction device comprising a helmet, support means and distraction means for applying distraction forces to a user's jaw area. Mathues discloses that the helmet can be plastic (polymer) or plaster, and that the helmet be strong enough to support the support means and distraction means, but does not specify other components of the helmet.

Schwenn et al. disclose a helmet for applying distracting forces to a wearer's head. Schwenn et al. specify that the helmet be made of a co-polymer (polypropylene), and that the helmet be custom-fitted to the wearer (see column 3, lines 60-61). The helmet has adjustment means comprising a generally vertical slit (see figures) defining ends on the helmet, with closure means (8) for securing the ends. The helmet comprises an internally disposed compressible liner (foam), which is an internally disposed shaping member. Schwenn et al. specify that these elements provide a secure connection of the helmet to the user's head.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the device disclosed by Mathues, wherein the helmet comprises a custom-fitted polymer helmet having adjustment means, a liner and shaping members, as taught by Schwenn et al., to provide a secure fit of the helmet to the user's head.

13. Claims 7-8, 10-12, 14, 29-30, 33-34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle in view of U.S. Patent Number 6,428,494 to Schwenn et al.

Doyle discloses the previously described craniomaxillofacial distraction device comprising a helmet, support means and distraction means for applying distraction forces to a

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user's jaw area. Doyle discloses that the helmet be strong enough to support the support means and distraction means, but does not specify other properties of the helmet.

Schwenn et al. disclose a helmet for applying distracting forces to a wearer's head. Schwenn et al. specify that the helmet be made of a co-polymer (polypropylene), and that the helmet be custom-fitted to the wearer (see column 3, lines 60-61). The helmet has adjustment means comprising a generally vertical slit (see figures) defining ends on the helmet, with closure means (8) for securing the ends. The helmet comprises an internally disposed compressible liner (foam), which is an internally disposed shaping member. Schwenn et al. specify that these elements provide a secure connection of the helmet to the user's head.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the device disclosed by Doyle, wherein the helmet comprises a custom-fitted polymer helmet having adjustment means, a liner and shaping members, as taught by Schwenn et al., to provide a secure fit of the helmet to the user's head.

14. Claims 10, 13, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathues in view of U.S. Patent Number 6,423,019 to Papay et al.

Mathues discloses the previously described craniomaxillofacial distraction device comprising a helmet, support means and distraction means for applying distraction forces to a user's jaw area. Mathues discloses that the helmet can be plastic (polymer) or plaster, and that the helmet be strong enough to support the support means and distraction means, but does not specify other components of the helmet.

Papay et al. disclose a helmet for applying distracting forces to a wearer's head. Papay et al. specify that the helmet be made of a clear polymer, and that the helmet includes adjustment means, in the form of inflatable bladders (20), to ensure proper fit of the helmet.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the device disclosed by Mathues, wherein the helmet comprises a polymer helmet having inflatable bladders, as taught by Schwenn et al., to ensure proper fit of the helmet.

15. Claims 10, 13, 32 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Doyle in view of U.S. Patent Number 6,423,019 to Papay et al.

Doyle discloses the previously described craniomaxillofacial distraction device comprising a helmet, support means and distraction means for applying distraction forces to a user's jaw area. Doyle discloses that the helmet can be strong enough to support the support means and distraction means, but does not specify other components of the helmet.

Papay et al. disclose a helmet for applying distracting forces to a wearer's head. Papay et al. specify that the helmet be made of a clear polymer, and that the helmet includes adjustment means, in the form of inflatable bladders (20), to ensure proper fit of the helmet.

It would have been obvious to one skilled in the art at the time the invention was made to have provided the device disclosed by Doyle, wherein the helmet comprises a polymer helmet having inflatable bladders, as taught by Schwenn et al., to ensure proper fit of the helmet.

Allowable Subject Matter

16. Claims 47-49 are allowed, per the resolution of the Claim Objections noted above.

17. Claims 16-19 and 37-40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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18. The following is an examiner's statement of reasons for allowance: The relevant prior art does not disclose nor fairly suggest the claimed craniomaxillofacial distraction device having helmet that distributes compressive forces such that localized pressure points are avoided, and having a pair of distraction assemblies each comprising a threaded distraction screw, a spindle housing and bone attachment means. Regarding the specifics of the pairs of distraction assemblies, U.S. Patent Number 3,072,118 discloses the most relevant prior art, however '118 teaches away from the user of such distraction assemblies with a helmet that distributes compressive forces and avoids localized pressure points.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda F. Wieker whose telephone number is 571-272-4794. The examiner can normally be reached on Monday-Thursday, 7:30 - 5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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Amanda F. Wieker
Examiner
Art Unit 3743


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